

In re Application of:
Lee *et al.*
Application No.: 09/361,655
Filed: July 27, 1999
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PATENT
Attorney Docket No.: JHU1220-4

THE DECLARATION:

The Office Action alleges that the Declaration filed on July 27, 1999, is defective. Applicants submit that in the transmittal of the present divisional application two Declarations were filed. One Declaration was defective by referring to the wrong PCT, however, a second "corrected" Declaration was also filed with the application transmittal that included the correct PCT number as well as correctly claiming priority under 35 U.S.C. §120.

REMARKS

These remarks are in response to the Office Action dated August 29, 2000. Claims 15-22 are pending. Claims 15-16, 18, and 22 have been amended. Support for the amendment to claim 15 can be found, for example, at page 16, lines 25-26, and page 27, Example 2. Amendments to claims 16, 18, and 22 are to correct antecedent basis and a misspelling error. New claim 44 has been added. Support for claim 44 can be found throughout the specification and claims as originally filed (*e.g.*, claims 15-22, page 16, lines 25-26, and page 27, Example 2). Claim 17 has been canceled without prejudice to Applicants' right to prosecute the canceled subject matter in any divisional, continuation, continuation-in-part or other application. Accordingly, no new matter has been added. Following entry of the foregoing amendments and claims, claims 15-16, 18-22, and 44 are pending. Applicants respectfully request reconsideration of the application and allowance of the claims now pending.

I. REJECTIONS UNDER 35 U.S.C. §101

Claims 15-22 stand rejected under 35 U.S.C. §101 as allegedly lacking either a specific and substantial asserted utility or a well established utility. Claim 17 has been canceled, thus rendering the rejections moot with respect to this claim. Applicants respectfully traverse this rejection.

Claim 15, upon which claims 16-22 are dependent, and claim 44 recite a method whereby differences in GDF-12 in a liver specimen are measured and compared to a control, or normal specimen wherein a difference is indicative of a disorder or abnormal GDF-12 expression. As

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demonstrated in Example 2 at page 27, GDF-12 is primarily expressed in the liver. Established diagnostics measure changes in proteins found in a tissue as indicative of a metabolic or cellular change in the tissue and potentially indicative of a disorder. For example, tumorigenesis and tumor growth can be assessed using a variety of cell proliferation markers (for example Ki67, cyclin D1 and proliferating cell nuclear antigen (PCNA), estrogen, epidermal growth factor (EGF), erbB-2, transforming growth factor (TGF) alpha, insulin growth factor (IGF) receptors, or EGF receptor). Similarly, liver enzymes (*e.g.*, alkaline phosphatase), clotting factors (*e.g.*, fibrinogen, prothrombin, and the like) and other factors are routinely measured to determine changes in liver metabolism and hepatocyte activity. The claims as amended have a specific and substantial asserted utility as well as an established utility, namely, measuring metabolic changes in the liver as an indicator of liver or hepatocyte function. One of skill in the art would recognize in light of the present specification that measuring changes in GDF-12 has a credible real world utility as a liver function marker. In addition, the claimed methods provide a clear result that is not the object of further research as alleged in the present Office Action (see page 4, second sentence from bottom). Accordingly, Applicants respectfully request withdrawal of the §101 rejection.

II. REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 15-22 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to adequately teach how to use the instant invention. The Office Action alleges, "since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention." (Office Action at page 5, first full paragraph). Claim 17 has been canceled, thus rendering the rejections moot with respect to this claim. Applicants respectfully traverse this rejection.

As stated above with respect to the §101 rejection, the claimed invention provides a clearly measurable result having a specific, substantial and well established utility. One skilled in the art would recognize, based upon the specification and particularly the data provided in Example 2, that changes in the specific expression of GDF-12 in the liver would be indicative of

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cellular metabolic changes in the liver. Such information does not require additional research as the results of the claimed method would provide a measurable result, for example, either GDF-12 being higher, lower or the same as that found in a control or normal specimen. Accordingly, Applicants respectfully request withdrawal of the §112, first paragraph rejection.

III. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 15-22 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 has been canceled, thus rendering the rejections moot with respect to this claim. Applicants respectfully traverse this rejection.

Claim 15 has been amended to provide a result and to provide the correct spelling of the term "specimen". Applicants believe that these amendments overcome the rejection and respectfully request withdrawal of the §112, second paragraph rejection.

In view of the above remarks, reconsideration and favorable action on all claims is respectfully requested. Should any questions remain in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: 11/28/00



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